

*NOTE: See NIH website for data safety guidelines and templates per Institute:*  
<https://grants.nih.gov/policy/humansubjects/policies-and-regulations/data-safety.htm>

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**[RESEARCH ORGANIZATION]**

**[STUDY NAME]**

**Data Safety and Monitoring Board (DSMB) Charter**  
revised [Date]

**Study Overview:**

**Sites:**

**Participants:**

**Recruitment Timeline:**

**Evaluation Measures:**

**Data Safety and Monitoring Board (DSMB) Charter:**

**DSMB Overview:** The study will have a DSMB to provide independent safety review and trial guidance during the course of the ongoing study. Throughout the study period, the DSMB will review study processes and progress, adverse event data, and outcomes across treatment groups in order to judge whether the overall safety and feasibility of the trial remains acceptable. The DSMB may recommend a new course of action for a specific treatment group or may suggest other appropriate courses of action to address general study safety issues which may arise. If warranted, the DSMB may recommend at any time that the entire protocol be suspended temporarily or terminated permanently. These recommendations will be directed to the study sponsor which has the responsibility to accept, reject or modify DSMB recommendations.

**Specific Responsibilities of the DSMB:** The specific responsibilities of the study DSMB are listed below:

- Evaluate the progress of the trial, including periodic assessments of data quality and timeliness, recruitment, accrual and retention, participant risk versus benefit, performance of the trial sites, and other factors that can affect study outcomes.
- Consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial.
- Review study performance, make recommendations and assist in the resolution of problems reported by the Principal Investigator.
- Protect the safety of the study participants.
- Report to [SPONSOR] on the safety and progress of the trial.

- Make recommendations to [SPONSOR] and the Principal Investigator concerning continuation, termination or other modifications of the trial based on the observed beneficial or adverse effects of the intervention.
- If appropriate, review interim analyses in accordance with stopping rules, which are clearly defined in advance of data analysis.
- Ensure the confidentiality of the study data.
- Comment on any problems with study conduct, enrollment, sample size and/or data collection.
- Attend scheduled meetings and prepare a written report following each meeting. The report will be in the form of a letter to the study sponsor, and it will be signed by the DSMB Chair.

**Specific Responsibilities of the Investigator Team:** The specific responsibilities of the [STUDY NAME] investigator team, with regard to DSMB activities, are listed below.

- Schedule, coordinate and host bi-annual DSMB meetings.
- Prepare summary minutes for the open portion of each DSMB meeting and maintain all meeting records.
- Prepare and provide materials and data to be reviewed by the DSMB, including:
  - A bi-annual report on study progress, data collection and analysis, results as available, and a summary of adverse event data (blinded). The report will be emailed to the DSMB at least five working days prior to each bi-annual meeting.
  - A separate bi-annual report with unblinded adverse event data (SAE and AE). The report will be emailed to the DSMB at least five working days prior to each bi-annual meeting.
  - A quarterly report listing all SAEs reporting during that quarter. The report will be emailed to the DSMB on a quarterly basis each year.
  - Ad hoc data summaries or study documents as requested by the DSMB.
- Forward reports twice yearly to IRB along with minutes from alternating quarterly calls with DSMB.

**DSMB Members:** The DSMB will have [INSERT NUMBER OF MEMBERS AND EXPERTISE] (*e.g., three members: a senior prevention research expert; a Tribal health leader with Tribal research ethics expertise; and a biostatistics expert*). All three members are external to the investigator team.

One of the members will serve as the DSMB Chair and will be responsible for drafting and submitting reports following each meeting.

**Meeting Schedule:** The DSMB will meet at least once each year, until the final study participant has completed the study. The meeting will be hosted by the Investigator team and field-based staff members.

**Meeting Format:** Meetings will consist of open and closed sessions. During the initial open portion of a meeting, the investigator team will briefly review the study data and progress as outlined in the bi-annual DSMB report and the investigators will be available for questions from DSMB members. The remaining closed portion of the meeting will take place with only the DSMB members in attendance. The final open portion of the meeting will occur during which time the DSMB members will summarize for the investigators the recommendations they plan to submit to the sponsor.

**Remuneration:** The DSMB Chair will receive [DOLLAR AMOUNT] per year, and the two additional DSMB members will each receive [DOLLAR AMOUNT] per year, to be paid by [GRANTEE INSTITUTION] with funds from the [SPONSOR/GRANT] for the [STUDY].